

PLAINTIFF SUN PHARMACEUTICAL INDUSTRIES LIMITED'S
COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Sun Pharmaceutical Industries Limited (“Sun”), by and through its counsel, respectfully submits this Complaint for Declaratory Judgment against Defendants Novartis Pharmaceuticals Corp. and Novartis AG (“Novartis”). In support thereof, Sun alleges as follows:

NATURE OF THE ACTION

1. This action is based on the patent laws of the United States, Title 35 of the United States Code. Sun brings claims for declaratory relief that Novartis’ U.S. Patent No. 9,283,209 (“the ‘209 patent”) is invalid, unenforceable and/or is not infringed by Sun thereby allowing the Federal Food and Drug Administration (“FDA”) to approve Sun’s application to market its generic version of deferasirox that is bioequivalent to Novartis’ drug Jadenu®.

THE PARTIES

2. Plaintiff Sun is a corporation organized and existing under the laws of the India, with its principal place of business in Mumbai, India.

3. On information and belief, Defendant Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

4. On information and belief, Defendant Novartis AG is a corporation organized and existing under the laws Switzerland and has its principal place of business in Basel, Switzerland.

JURISDICTION AND VENUE

5. This is a civil action regarding allegations of patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, in which Sun seeks declaratory relief under the Declaratory Judgment Act. Thus, the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

6. An actual controversy exists between Sun and Novartis by virtue of Novartis' listing of the '209 patent in the Orange Book for Jadenu®, Sun's filing of ANDA No. 211641 (the "Sun ANDA") with the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) for a generic version of deferasirox that is bioequivalent to Novartis' drug Jadenu® and Novartis' refusal to covenant to Sun that it will not bring an action for patent infringement with respect to Sun's ANDA No. 211641 or any product described therein.

7. Sun contends that it has a right to engage in making, using, offering to sell, and selling its products described in the Sun ANDA without license from Novartis.

8. This Court has personal jurisdiction over Novartis because Novartis conducts substantial business in, and has regular and systematic contact with, the State of New Jersey, including this District.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Novartis is subject to personal jurisdiction in this District.

REGULATORY BACKGROUND

10. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. §355 and 35 U.S.C. §§ 156 and 271(e). The Hatch-Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by "branded" drug companies. *See* H.R. Rep No. 98-857, pt. 1 at 14-15 (1984). The Hatch-Waxman Act was designed to stem the rising cost of prescription drugs by bringing less expensive generic drugs to market faster.

11. Pursuant to the Hatch-Waxman Act, a brand-name drug sponsor seeking FDA approval of a new drug must submit a New Drug Application ("NDA"). *See* 21 U.S.C. § 355.

The NDA must include specific data concerning the safety and effectiveness of the drug, as well as identification of every patent that claims the “drug or method of using the drug.”

12. The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file a lengthy and costly NDA in order to obtain FDA approval to sell a generic equivalent of a marketed drug. Instead, FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application (“ANDA”).

13. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer must demonstrate to FDA the proposed generic product is bioequivalent to the reference listed drug (“RLD”).

14. As a counter-balance to the abbreviated process for bioequivalent generic drug products, the Hatch-Waxman Act also provided NDA holders certain non-patent exclusivities, such as Orphan Drug and New Chemical Entity (“NCE”) exclusivities.

15. When FDA approves a brand name manufacturer’s NDA, FDA publishes in the “Orange Book” any patents the brand manufacturer alleges can be reasonably asserted against a generic equivalent. 21 U.S.C. §355(j)(7)(A)(iii). The listing of patents in the Orange Book by FDA is a ministerial act. FDA does not check the facts supplied to it by the brand manufacturer.

16. After NDA approval by FDA, the NDA holder may list additional new patents in the Orange Book as being related to the drug the subject of the NDA. The brand manufacturer must certify the new patents claim either the approved drug or approved methods of the using the drug.

17. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a branded drug without receiving a license from the NDA holder), the ANDA must contain

one of four certifications for each patent listed in the Orange Book for the RLD: (i) there are no patents listed in the Orange Book; ii) any listed patent has expired; (iii) the patent will have expired before the generic manufacture is seeking to market its generic product; or (iv) the patent is invalid, unenforceable or will not be infringement by the manufacture, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. §355(j)(2)(A)(vii)(I-IV). The last of these is commonly referred to as a paragraph IV certification.

18. An ANDA applicant who files a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. §355(J)(2)(B)(i).

19. An ANDA applicant may bring a declaratory judgment action for invalidity and/or non-infringement of an Orange Book listed patent if the NDA holder does not sue the ANDA holder within 45 days of receiving notice of the ANDA holder's paragraph IV certification. 21 U.S.C. §355(J)(5)(C).

SPECIFIC FACTUAL ALLEGATIONS

20. The '209 patent, entitled "Oral Formulations of Deferasirox," was issued on March 15, 2016. As per the face of the patent, the inventors of the subject matter claimed in the '209 patent are Indrajit Ghosh and Jia-Ai Zhang, and Novartis AG is the purported assignee of record. A true and correct copy of the '209 patent is attached hereto as Exhibit A.

21. The '209 patent purports to claim reduced and fast release orally administrable formulations of deferasirox.

22. Novartis markets and sells deferasirox tablets under the brand name Jadenu®. Novartis submitted a New Drug Application ("NDA") to the FDA for Jadenu® tablets for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older and for the treatment of chronic iron overload in patients 10

years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L (No. 206910).¹ Upon information and belief, NDA No. 206910 was approved by the FDA on or about March 30, 2015, for Jadenu® tablets in strengths of 90 mg, 180 mg and 360mg.

23. The '209 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") as covering Jadenu®.

24. On March 29, 2018, Sun Pharmaceutical Industries, Inc., on behalf of Sun filed ANDA No. 211641 with the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).

25. Sun submitted ANDA No. 211641 with FDA seeking approval to manufacture and sell generic versions of deferasirox tablets that are bioequivalent to Novartis' drug Jadenu®.

26. Novartis caused two patents to be listed in FDA's Orange Book as covering Jadenu®: U.S. Patent No. 6,465,504 ("the '504 patent") and the '209 patent. As a result, under the Hatch-Waxman Act, Sun was required to submit patent certification to the '504 and '209 patents.

27. Sun's ANDA No. 211641 contains a paragraph III certification to the '504 patent certifying Sun will wait until the expiration of the '504 patent to begin marketing Sun's ANDA. The '504 patent expires on April 5, 2019.² Sun's ANDA also contains a paragraph IV

¹ Novartis Pharmaceutical Corp. is listed as the owner of the Novartis' NDA.

² NDA 206910 also has an exclusivity expiration of January 23, 2020, for treatment of chronic iron overload in patients 10 years and older with non-transfusion dependent thalassemia (NTDT) syndromes and with a liver iron concentration of at least 5 mg of iron per gram of liver dry weight and serum ferritin greater than 300 mcg/l.

certification that Sun's ANDA products will not infringe the '209 patent and/or the '209 patent is invalid or unenforceable.

28. Pursuant to Sun's paragraph IV certification, Sun seeks approval to engage in the commercial manufacture, use or sale of generic deferasirox tablets in strengths of 90 mg, 180 mg and 360 mg.

29. On June 11, 2018, Sun notified Novartis of the paragraph IV certification for the '209 patent, including the preliminary legal and factual basis for its position of non-infringement and invalidity and provided an Offer of Confidential Access to its ANDA.

30. Novartis did receive access to Sun's ANDA under the terms of a negotiated Offer of Confidential Access and Novartis did not sue Sun for patent infringement within 45 days of receiving notice of Sun's paragraph IV certification.

31. Sun requested Novartis covenant it would not sue Sun for patent infringement relating to the filing of ANDA No. 211641 and the product described therein. Novartis has not agreed to Sun's request.

32. As Novartis has not sued Sun for patent infringement and has provided Sun no assurances it will not sue Sun for infringement of the '209 patent, Sun filed this declaratory judgment action seeking a declaration that Sun's ANDA products will not infringe the '209 patent in order to enable Sun to bring its products to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions.

33. Sun believes that the claims of the '209 patent are not infringed, are invalid and/or are unenforceable. Accordingly, an actual controversy exists between Sun and Novartis as to whether Sun's ANDA infringes any valid and enforceable claim of the '209 patent. Absent a declaration of noninfringement, invalidity and/or unenforceability, the listing of the '209 patent

in the Orange Book will effectively deny Sun an economic opportunity to enter the marketplace and leave Novartis open to suing Sun at any time before the expiration of the '209 patent on November 21, 2034.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT)

34. Sun hereby incorporates by reference its allegations contained in paragraphs 1 through 33 of this Complaint as though fully set forth herein.

35. This claim arises under the Patent Laws of the United States, 35 U.S.C. §1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Hatch-Waxman Act, 21 U.S.C. §355(j)(5)(C).

36. Novartis has listed the '209 patent in the Orange Book as covering its Jadenu® tablets.

37. Sun has filed an ANDA with a paragraph IV certification stating the '209 patent is not infringed by Sun.

38. Sun intends to sell deferasirox tablets, as described in ANDA No. 211641, when it obtains final FDA approval.

39. There is a real, actual and continuing justiciable case and controversy between Sun and Novartis regarding the infringement of the '209 patent.

40. The '209 patent will not be infringed by the manufacture, use or sale of generic deferasirox tablets for which Sun has submitted ANDA No. 211641.

41. Accordingly, Sun seeks and is entitled to a judicial declaration that the manufacture, sale or use of Sun's deferasirox tablets, the subject of ANDA No. 211641, will not infringe, directly or indirectly, any valid claim of the '209 patent.

PRAYER FOR RELIEF

WHEREFORE, Sun prays for a declaratory judgment against Novartis as follows:

A. Judgment against Novartis declaring that the ‘209 patent is not infringed by the filing of Sun’s ANDA No. 211641;

B. Declaring the manufacture, marketing, use or offer for sale, sale and/or importation of the products that are the subject of Sun’s ANDA No. 211641 have not infringed, do not infringe and would not, if marketed, infringe or induce or contribute to the infringement of any valid claim of the ‘209 patent;

C. Awarding Sun its costs, expenses and reasonable attorneys’ fees pursuant to 35 U.S.C. §285; and

D. Awarding Sun such other and further relief as the Court deems just and reasonable.

Dated: January 9, 2019

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: January 9, 2019

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that plaintiff seeks, *inter alia*, declaratory relief.

Dated: January 9, 2019

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